

**EPA Registration No. 72977-6**



**72977-6**



**009283572**

Explore Registrations

Reg Number: 72977-A

Reg. Type: Product Registration - Section 3

Status: Under Review (20-Apr-2009)

Name: SDC0240CP

<View Registration Details>

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

...Decisions...

Data Requirements

D: Pending; 409004; 72977-A; A532; UNREGISTERED

Decision Sequence: 409004

Action: A532 UNREGISTERED SOURCE OF ACTIVE INGREDIENT; M

Number: 72977-A Original Decision:

Name: SDC0240CP

Decision Status: PENDING (22-Apr-2009)

Organization Owner: AD / RMB1

Team Owner: RM 33

FFS Start Date 11-May-2009 Received by Risk Manager:

Due Date 11-Sep-2009 FFS Amt Expected: \$4,410

Negotiated Due Date: FFS Amt Refunded:

FFS Amt Received: \$4,410

Comments:

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 24VDB688

Agency Tracking ID: 74068629769

Transaction Date and Time: 04/13/2009 18:20 EDT

Payment Summary

Address Information

Account Holder Name: Dolana Jonte  
1725 Gillespie

Billing Address: Way

Billing Address 2:

City: El Cajon

State / Province: CA

Zip / Postal Code: 92020

Country: USA

Account Information

Card Type: Master Card

Card Number: \*\*\*\*\*4051

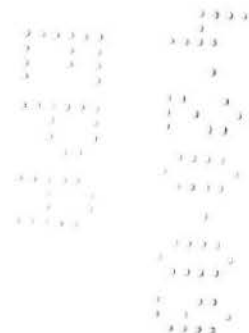
Decision Number:

Registration Number: 72977-A

Payment Information

Payment Amount: \$4,410.00

Transaction Date 04/13/2009 18:20  
and Time: EDT



# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 4.20.09

Experts In-Processing Signature: M F HARRINGTON Date 4.23.09

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>72977-1A</u>		EPA Receipt Date: <u>4.20.09</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes X	no 		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes ✓	no 		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X		
	a) Selective Method (Fee category experts use)	yes X	no 		
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )		X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)			X
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:** There is no data associated with this jacket

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web



site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/opppbd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/opppbd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### **Unapproved Inerts Identified on CSFs**

##### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



RE: Application for Registration of SDC0240CP  
Brown, Elizabeth to: Jennifer Drobish

04/27/2009 11:29 AM

Attached please find the revised form for the above pending application  
(File Symbol 72977-A)

-----Original Message-----

From: Drobish.Jennifer@epamail.epa.gov  
[mailto:Drobish.Jennifer@epamail.epa.gov]  
Sent: Monday, April 27, 2009 11:21 AM  
To: Brown, Elizabeth  
Subject: Application for Registration of SDC0240CP

Dr. Brown

This is Jennifer Drobish, EPA contractor. I'm writing regarding your submission in support of the application for registration of SDC0240CP. We found a deficiency regarding the application package. The Certification with Respect to Citation of Data (EPA Form 8570-34) is inconsistent with the Data Matrix (EPA Form 8570-27). This can be fixed by selecting the selective method on the Certification, as there is a cite-all option under it. The corrections can be faxed to 703-305-5060/Attn: Jennifer Drobish or emailed to drobish.jennifer@epa.gov.

Thank you  
Jennifer Drobish  
EPA Contractor  
703-305-1671



20090427.EPA Form 8570-34 Cert wrt data citation SDC0240CP.pdf

# **FEE FOR SERVICE**

# ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: <i>4/20/09</i>		EPA Reg. Number: <i>72977-A</i>		
	Check List Item	Yes	No	N/A
1	Has the <b>PRIA Fee been Paid</b> ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an <b>Application Form</b> (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a <b>Confidential Statement of Formula</b> (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a <b>Formulator's Exemption Statement</b> (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a <b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a <b>Data Matrix</b> (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a <b>Label</b> Included in the Submission Package?	X		
8	Are <b>Data</b> Included in the Submission Package?		X	
9	Is the Submission an Amendment?		X	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

ETI H20  
1725 Gilliespie Way  
El Cajon, CA 92020

OCT 9 2009

Agent: Steptoe and Johnson  
1330 Connecticut Avenue, N.W.  
Washington, D.C. 20036-1795

Attention: Elizabeth Anne Brown, PHD

Subject: SDC0240P  
EPA Registration No. 72977-6  
Amendment Dated October 7, 2009

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

- To address label wording modifications in the Directions for use

A stamped copy of the "accepted" product labeling is enclosed for your records.

If you have any questions regarding this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Swindell".

Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)

Enclosure

## SDC0240CP

Bacteriostatic Humidifier Water Treatment

[Controls build up of bacteria and algae in water tanks of [portable] [and/or] [console] humidifier[s]  
[units]]

### Active Ingredients

Silver\* 0.24%

Citric Acid 20.66%

Other Ingredients 79.10%

Total .....100.00%

\* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

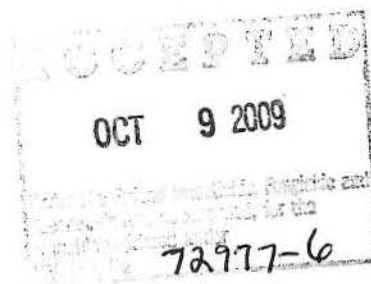
### CAUTION

See [side panel] [inside label] for additional precautionary statements]

EPA REG. No. 72977-6  
EPA EST. No. XXXXX-XX-XXX  
Manufactured by ETI H<sub>2</sub>O,  
A Division of PURE Bioscience  
1725 Gillespie Way  
El Cajon, CA 92020

[Batch number – may appear on bottle]

Net Contents:



**NOTE TO REVIEWER:** [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.



**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is for the control of bacteria and algae in humidifier water tanks. Thoroughly clean humidifier water tank and filters before each heating season. SDC0240CP is designed for use in portable [and/or console] humidifiers. SDC0240CP is not for use in heat vaporizing or atomizing type vaporizer humidifiers.

***Note to reviewer: The following directions will be used for containers that do not include a dosing device/dropper.***

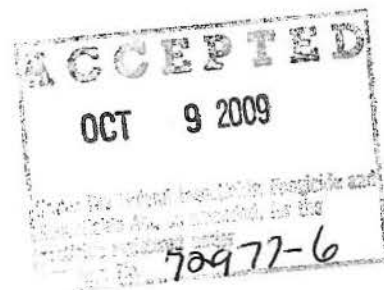
For every 3 gallons of water contained in the humidifier tank, add one teaspoon (5 ml) of [SDC0240CP] [this product]. Repeat this process when refilling tank.

This product will stain fabrics if contacted.

***Note to reviewer: The following directions will be used for containers that include a dosing device/dropper.***

For every half gallon of water added to the humidifier tank, add one dropper filled to the double line (0.75 ml or 0.025 fl. oz.) with [SDC0240CP] [this product]. Do not use the dropper for any other purpose.

This product will stain fabrics if contacted.



**NOTE TO REVIEWER:** [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>HOT LINE NUMBER</b></li> </ul>	
<ul style="list-style-type: none"> <li>• Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.</li> </ul>	

STORAGE AND DISPOSAL
<p>Do not contaminate water, food or feed by storage or disposal.</p> <p><b>Pesticide Storage:</b> Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container in areas inaccessible to individuals unfamiliar with use.</p> <p><b>Pesticide Disposal and Container Handling:</b> Nonrefillable Container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.</p>

*Optional phrases for labeling or label packaging.*

Ready to use

Odorless

Colorless

Non-corrosive to humidifier parts

Controls buildup of bacteria and algae in portable [and/or console] humidifier water tanks

Control odors caused by bacteria and algae in portable [and/or console] humidifier water tanks

For use in manually filled humidifier water tanks

Easy to use

Powered by [SDC Ag+] [Silver science] [SDC]

Patented Formula

US Patents [insert applicable patent number(s)]

Helps control bacteria in water tanks

Helps control algae build-up in water tanks

[Helps] Eliminate[s] unpleasant odors

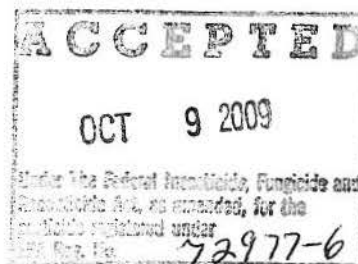
[For] use in evaporative [cool mist] humidifiers

Made in the USA [include us flag symbol]

Results may vary according to water quality

Dosing Dropper included *Note: Based upon container*

[One bottle] treats XX gallons *Note: Based upon container size*



**NOTE TO REVIEWER:** [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.

# Material to be added to an e-Jacket/Jacket

Reg. No. 72977-6

1. ☒ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top/newest)
  - ☐ Description: (PDF page number, i.e., "before page 45")
- \_\_\_\_\_
- \_\_\_\_\_

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF

☒ Other: New Registration

3. Attach this coversheet to the top of the material or jacket. must be well organized and clipped together, NOT STAPLED Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: K Leavy

Phone: 308-6217 Division: AD

Date: 9/11/09

DECISION PKG. NO. 409004

SUBM. DUE DATE 9/11/09

SUBMISSION BAR CODE # 848800

REVIEWER KL

**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**

FILE SYMBOL/REG NO. 72277-6 PM 33 ACTION CODE PRIA

DESCRIPTOR New Reg **FQPA** **NFQPA**

☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIRED

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

4.20.09

4.20.09

4.20.09

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE  
☐ NOT SUBMITTED ☐ N/A

☐ SUBMITTED ☐ NOT SUBMITTED  
☐ N/A

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY ☐ ☐ ☐ ☐

EFFICACY ☐ ☐ ☐ ☐

ACUTE TOX. ☐ ☐ ☐ ☐

RASSB TOX. ☐ ☐ ☐ ☐

ENVIRON. FATE ☐ ☐ ☐ ☐

FISH/WILDLIFE ☐ ☐ ☐ ☐

OTHER: ☐ ☐ ☐ ☐

STATUS \_\_\_\_\_

RESPONSE CODE 1160

RESPONSE DATE 9/11/09



U.S. ENVIRONMENTAL PROTECTION  
AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

72977-6

Date of Issuance:

SEP 11 2009

Term of Issuance:

Unconditional

Name of Pesticide Product:

SDC0240CP

Name and Address of Registrant (include ZIP Code):

ETI H2O  
A Division of PURE Bioscience  
1725 Gillespie Way  
El Cajon, CA 92020

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 72977-6".

Signature of Approving Official:

Marshall Swindell  
Product Manager-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Date:

SEP 11 2009

b. On the front page of the label change "Humidifier Bacteriostat" to "Bacteriostatic Humidifier Water Treatment".

c. Change the Use Directions section of the label to read as follows:

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product is for the control of bacteria and algae in humidifier water tanks. Thoroughly clean humidifier water tank and filters before each heating season. SDCO240CP is not for use in heat vaporizing or atomizing type vaporizer humidifiers.

- A. For container sizes 8 oz and smaller: For every half gallon of water added to the humidifier tank, add one dropper (provided) filled to the double line (0.75 ml) or 0.025 fl. Oz.) with [SDCO240CP][this product]. Repeat this process when refilling the tank.
- B. For container sizes larger than 8 fl.oz.: For every 3 gallons of humidifier tank water add one teaspoon (5 fl. oz) of [SDCO240CP][this product]. Repeat this process when refilling the tank.

This product will stain fabrics if contacted.

d. Delete the following label statements:

"non-corrosive", "[without bleaching]", "Other patents pending", and "Powered by [SDC Ag+]".

e. Add the statement "Keep Out Of Reach Of Children" immediately below the statement "Hazards To Humans And Domestic Animals".

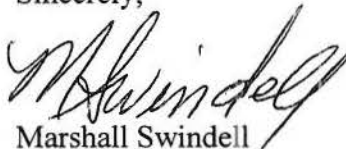
3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

The Confidential Statement of Formula dated April 16, 2009 is acceptable.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)

Enclosure: Stamped Labeling

**SDC0240CP**

Humidifier Bacteriostat

[Controls build up of bacteria and algae in water tanks of [portable] [and/or] [console] humidifier[s]  
[units]]

**Active Ingredients**

Silver\* 0.24%

Citric Acid 20.66%

**Other Ingredients** 79.10%**Total** ..... 100.00%

\* Electrolytically generated Silver ions

**ACCEPTED**  
with COMMENTS  
in EPA Letter Dated

SEP 11 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

72977-6

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See [side panel] [inside label] for additional precautionary statements]

EPA REG. No. 72977-#

EPA EST. No. XXXXX-XX-XXX

Manufactured by ETI H<sub>2</sub>O,  
A Division of PURE Bioscience  
1725 Gillespie Way  
El Cajon, CA 92020

[Batch number – may appear on bottle]

Net Contents:

NOTE TO REVIEWER: [Bracketed text] is optional wording. Bold and italicized text in  
informational only and not part of the label. Batch number may be placed on the label or on the  
container itself.



# DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

SDC0240CP is designed for use in portable [and/or console] humidifiers.

***Note to reviewer: The following directions will be used for containers that do not include a dosing device/dropper.***

For every gallon of water contained in the humidifier tank, add 1.5 mL (0.05 fl. oz.) of [SDC0240CP] [this product]. Repeat this process when refilling tank.

This product will stain fabrics if contacted.

***Note to reviewer: The following directions will be used for containers that include a dosing device/dropper.***

For every half gallon of water added to the humidifier tank, add one dropper filled to the double line (0.75 ml or 0.025 fl. oz.) with [SDC0240CP] [this product]. Do not use the dropper for any other purpose.

This product will stain fabrics if contacted.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
SEP 11 2009  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 72977-6

NOTE TO REVIEWER: [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.

21

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<ul style="list-style-type: none"> <li><b>HOT LINE NUMBER</b></li> </ul>	
<ul style="list-style-type: none"> <li>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.</li> </ul>	

STORAGE AND DISPOSAL
<p>Do not contaminate water, food or feed by storage or disposal.</p> <p><b>Pesticide Storage:</b> Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container in areas inaccessible to individuals unfamiliar with use.</p> <p><b>Pesticide Disposal and Container Handling:</b> Nonrefillable Container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.</p>

#### *Optional phrases for labeling or label packaging.*

Ready to use

Odorless

Colorless

Non-corrosive

Controls buildup of bacteria and algae in portable [and/or console] humidifier water tanks [without bleach(ing)]

Control odors caused by bacteria and algae in portable [and/or console] humidifier water tanks

For use in manually filled humidifier water tanks

Easy to use

Powered by [SDC Ag+] [Silver science] [SDC]

Patented Formula

US Patents [insert applicable patent number(s)]

Other patents pending

Helps control bacteria in water tanks

Helps control algae build-up in water tanks

[Helps] Eliminate[s] unpleasant odors

[For] use in evaporative [cool mist] humidifiers

Made in the USA [include us flag symbol]

Results may vary according to water quality

Dosing Dropper included *Note: Based upon container*

[One bottle] treats XX gallons *Note: Based upon container size*

**ACCEPTED  
with COMMENTS  
in EPA Letter Dated**

**SEP 11 2009**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. **72977-6**

**NOTE TO REVIEWER:** [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.

22



RE: Questions regarding use of Silver as an active ingredient in the formulation of the pending application for registration under EPA File Symbol # 72977-A

Karen Leavy to: Brown, Elizabeth

06/01/2009 03:18 PM

Elizabeth,

Thanks so much.

KML

"Brown, Elizabeth" Karen: There are no particles, and as such parti...

06/01/2009 03:17:00 PM

From: "Brown, Elizabeth" <eabrown@steptoe.com>  
To: Karen Leavy/DC/USEPA/US@EPA  
Cc: Betty Shackleford/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA, Dennis Edwards/DC/USEPA/US@EPA  
Date: 06/01/2009 03:17 PM  
Subject: RE: Questions regarding use of Silver as an active ingredient in the formulation of the pending application for registration under EPA File Symbol # 72977-A

Karen:

There are no particles, and as such particle size is not relevant. The silver is ionic (Ag in the +1 valence), stabilized in citric acid as silver dihydrogen citrate. The radius of the silver atom, since it is an atom and therefore is less than 1 nanometer. However, this is the same as naturally occurs for silver ions. This product is not nanotechnology.

Please let me know if there are any questions or if anything further is needed.

-----Original Message-----

From: Leavy.Karen@epamail.epa.gov [mailto:Leavy.Karen@epamail.epa.gov]  
Sent: Monday, June 01, 2009 2:27 PM  
To: Brown, Elizabeth  
Cc: Shackleford.Betty@epamail.epa.gov;  
Swindell.Marshall@epamail.epa.gov; Edwards.Dennis@epamail.epa.gov  
Subject: Questions regarding use of Silver as an active ingredient in the formulation of the pending application for registration under EPA File Symbol # 72977-A

Elizabeth,

I need to some information concerning the active ingredient, Silver, being used in the pending application for registration under EPA File Symbol # 72977-A.

- 1) Does the product contain silver in on a nano scale range?
- 2) A nano scale is 500 nm or less
- 3) If indeed it does, can you provide the particle size distribution?

Could you get back to me as soon as possible?

KML

DECISION PKG. NO. 409004  
SUBMISSION BAR CODE # 848800

SUBM. DUE DATE 9/11/09  
REVIEWER (17)

**CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS**

FILE SYMBOL/REG NO. F2977-A PM 33 ACTION CODE A532

DESCRIPTOR \_\_\_\_\_ **FQPA** **NFQPA**

☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIRED

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION  
04/20/09

EPA RECEIVE DATE  
04/20/09

PM RECEIVE DATE  
04/22/09

METHOD OF SUPPORT

☐ CITE-ALL ☐ SELECTIVE  
☐ NOT SUBMITTED ☐ N/A

FORMULATORS EXEMPTION

☐ SUBMITTED ☐ NOT SUBMITTED  
☐ N/A

REVIEW(S) REQUESTED

DATA  
PACK #

DATE  
SENT

DUE  
DATE

DATE  
RETURNED

CHEMISTRY \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

EFFICACY \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

ACUTE TOX. \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

RASSB TOX. \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

ENVIRON. FATE \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

FISH/WILDLIFE \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

OTHER: \_\_\_\_\_ : \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ] \_\_\_\_\_ ]

STATUS \_\_\_\_\_

RESPONSE CODE 1160

RESPONSE DATE 09/11/09

SCIENCE  
GROUP

DIVISION

BRANCH

SECTION

CSF  
Y/N

LABEL  
Y/N

CHEMISTRY AD EASSB CTT

EFFICACY AD EASSB EET



U.S. ENVIRONMENTAL PROTECTION  
AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

72977-6

Date of Issuance:

Term of Issuance:

Unconditional

Name of Pesticide Product:

SDC0240CP

Name and Address of Registrant (include ZIP Code):

ETI H2O  
A Division of PURE Bioscience  
1725 Gillespie Way  
El Cajon, CA 92020

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number 72977-6".

Signature of Approving Official:

Marshall Swindell  
Product Manager-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Date:

The Confidential Statement of Formula dated April 16<sup>th</sup>, 2009, is acceptable.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell  
Product Manager 33  
Regulatory Branch I  
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)



**SDC0240CP**

Humidifier Bacteriostat

[Controls build up of bacteria and algae in water tanks of [portable] [and/or] [console] humidifier[s]  
[units]]

**Active Ingredients**

Silver\* 0.24%

Citric Acid 20.66%

**Other Ingredients** 79.10%**Total** .....100.00%

\* Electrolytically generated Silver ions

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See [side panel] [inside label] for additional precautionary statements]

EPA REG. No. 72977-#

EPA EST. No. XXXXX-XX-XXX

Manufactured by ETI H<sub>2</sub>O,  
A Division of PURE Bioscience  
1725 Gillespie Way  
El Cajon, CA 92020

[Batch number – may appear on bottle]

Net Contents:

**NOTE TO REVIEWER:** [Bracketed text] is optional wording. **Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.**

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

SDC0240CP is designed for use in portable [and/or console] humidifiers.

***Note to reviewer: The following directions will be used for containers that do not include a dosing device/dropper.***

For every gallon of water contained in the humidifier tank, add 1.5 mL (0.05 fl. oz.) of [SDC0240CP] [this product]. Repeat this process when refilling tank.

This product will stain fabrics if contacted.

***Note to reviewer: The following directions will be used for containers that include a dosing device/dropper.***

For every half gallon of water added to the humidifier tank, add one dropper filled to the double line (0.75 ml or 0.025 fl. oz.) with [SDC0240CP] [this product]. Do not use the dropper for any other purpose.

This product will stain fabrics if contacted.

NOTE TO REVIEWER: [Bracketed text] is optional wording. Bold and italicized text in informational only and not part of the label. Batch number may be placed on the label or on the container itself.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## CAUTION

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>HOT LINE NUMBER</b></li> </ul>	
<ul style="list-style-type: none"> <li>• Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 for emergency medical treatment information.</li> </ul>	

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container in areas inaccessible to individuals unfamiliar with use.

**Pesticide Disposal and Container Handling:** Nonrefillable Container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

### *Optional phrases for labeling or label packaging.*

- ~ Ready to use
- ~ Odorless
- ~ Colorless
- Non-corrosive
- ~ Controls buildup of bacteria and algae in portable [and/or console] humidifier water tanks [without bleach(ing)]
- Control odors caused by bacteria and algae in portable [and/or console] humidifier water tanks
- For use in manually filled humidifier water tanks
- Easy to use
- ~ Powered by [SDC Ag+] [Silver science] [SDC]
- Patented Formula
- US Patents [insert applicable patent number(s)]
- ~ Other patents pending
- Helps control bacteria in water tanks
- Helps control algae build-up in water tanks
- [Helps] Eliminate[s] unpleasant odors
- [For] use in evaporative [cool mist] humidifiers
- Made in the USA [include us flag symbol]
- Results may vary according to water quality
- Dosing Dropper included *Note: Based upon container*
- [One bottle] treats XX gallons *Note: Based upon container size*

**NOTE TO REVIEWER:** [Bracketed text] is optional wording. Bold and italicized text is informational only and not part of the label. Batch number may be placed on the label or on the container itself.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number ETI H2O, Inc. 1725 Gillespie Way El Cajon, CA 92020 619-596-8600	EPA Registration Number/File Symbol 72977-A
Active Ingredient(s) and/or representative test compound(s) Silver (ionic) and Citric Acid	Date 4/15/2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood, residential indoor	Product Name SDC0240CP

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 4/27/2009	Typed or Printed Name and Title Dolana Blount Director of Regulatory Affairs
---------------	-------------------	--



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: April 13, 2009	EPA Reg No./ File Symbol 72977-A	Page 1 of 3
Applicant's/Registrant's Name and Address: ETI H2O, Inc. 1725 Gillespie Way El Cajon CA 92020	Product: SDC0240CP	
Ingredient: ionic silver (PC 72501) and citric acid (PC 21801)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
OPPTS 830.1550	Product Identity and Composition	45161001	ETI H2O	Own	FN 1
OPPTS 830.1600	Description of starting materials	45161001	ETI H2O	Own	FN 1
OPPTS 830.1650	Description of the formulation process	45161001	ETI H2O	Own	FN 1
OPPTS 830.1670	Discussion of formation of impurities	45161001	ETI H2O	Own	FN 1
OPPTS 830.1700	Preliminary Analysis	45161001	ETI H2O	Own	
OPPTS 830.1750	Certified limits	45161001	ETI H2O	Own	FN 1
OPPTS 830.1800	Enforcement analytical method	45623201	ETI H2O	Own	
OPPTS 830.6302	Color	45182101	ETI H2O	Own	
OPPTS 830.6303	Physical state	45182101	ETI H2O	Own	
OPPTS 830.6304	Odor	45182101	ETI H2O	Own	
OPPTS 830.6313	Stability to normal and elevated temperatures, metals, and metal ions	45182002	ETI H2O	Own	
OPPTS 830.6317	Storage Stability	45623201	ETI H2O	Own	
OPPTS 830.6318	Viscosity	45161001	ETI H2O	Own	
OPPTS 830.6319	Miscibility	45161001	ETI H2O	Own	
OPPTS 830.6320	Corrosion Characteristics	45623201	ETI H2O	Own	
OPPTS 830.6321	Dielectric breakdown voltage	45161001	ETI H2O	Own	
OPPTS 830.7300	Density	45182101	ETI H2O	Own	
OPPTS 830.6314	Oxidation/reduction	45161001	ETI H2O	Own	
OPPTS 830.6315	Flammability	45161001	ETI H2O	Own	
OPPTS 830.6315	Explosibility	45161001	ETI H2O	Own	
OPPTS 830.6312	pH	45182101	ETI H2O	Own	
OPPTS 830.7050	UV-Vis absorption	45161001	ETI H2O	Own	

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown Steptoe & Johnson, LLP, Authorized Agent	Date 4/13/2009
--	--	-------------------



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: April 13, 2009	EPA Reg No./ File Symbol 72977-A	Page 2 of 3
Applicant's/Registrant's Name and Address: ETI H2O, Inc. 1725 Gillespie Way El Cajon CA 92020	Product: SDC0240CP	
Ingredient: ionic silver (PC 72501) and citric acid (PC 21801)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7550	Partition coefficient	45161001	ETI H2O	Own	
OPPTS 830.7840	Water solubility	45161001	ETI H2O	Own	
OPPTS 830.7950	Vapor pressure	45161001	ETI H2O	Own	
OPPTS 830.7370	Dissociation constant	45161001	ETI H2O	Own	
OPPTS 870.1100	Acute oral toxicity	45016901	ETI H2O	Own	
OPPTS 870.1200	Acute dermal toxicity	45016902	ETI H2O	Own	
OPPTS 870.1300	Acute inhalation toxicity	waived	ETI H2O	Own	FN 2
OPPTS 870.2400	Acute eye irritation	45016903	ETI H2O	Own	
OPPTS 870.2500	Acute dermal irritation	45016904	ETI H2O	Own	
OPPTS 870.2600	Skin sensitization	45016905	ETI H2O	Own	
<b>GENERIC – CITRIC ACID</b>		WAIVED	All data waived by RED; reaffirmed as minimal risk at 68 FR 18550 (4/16/2003)		
<b>GENERIC – SILVER</b>		CITE-ALL	See attached list	pay	

FN 1: plus new Group A report submitted April 16, 2009 for Axenohl, EPA Reg No 72977-1 (Report No. Axenohl-09-GroupA)

FN 2: Agency letter of 6/21/2001 on EPA Reg No. 72977-1

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown Steptoe & Johnson, LLP, Authorized Agent	Date 4/13/2009
--	--	-------------------



Companies on 3-31-2009 PDSL to whom Offer to Pay Data Compensation letters were sent:				
707	ROHM & HAAS CO	ATTN: JAMES V. HAGAN	100 INDEPENDENCE MALL WEST	PHILADELPHIA, PA 191062399
10324	MASON CHEMICAL CO		721 W ALGONQUIN RD	ARLINGTON HEIGHTS, IL 60005
18869	KING-HOLLER INT		606 WILSHIRE BLVD SUITE 501	SANTA MONICA, CA 90401
37370	NATIONAL SAFETY ASSOCIATES, INC.		4260 EAST RAINES ROAD	MEMPHIS, TN 38118
37664	TELEDYNE WATER PIK		1730 EAST PROSPECT ST	FORT COLLINS, CO 80521
38688	C. H. DEXTER DIVISION		ONE ELM STREET	WINDSOR LOCKS, CT 6096
39444	KATADYN PRODUKTE	D/B/A KATADYN PRODUCTS, INC.	122 C STREET, N.W., SUITE 740	WASHINGTON, DC 20001
39938	NORTH AMERICAN SYSTEMS, INC.		24700 MILES ROAD	BEDFORD HTS., OH 44146
40810	CIBA CORPORATION		4090 PREMIER DRIVE	HIGH POINT, NC 27265
53735	KING TECHNOLOGY INC.		530 11TH AVENUE SOUTH	HOPKINS, MN 55343
59441	EASTMAN KODAK COMPANY	HEALTH, SAFETY AND ENVIRONMENT	1999 LAKE AVENUE	ROCHESTER, NY 146502208
67619	CLOROX PROFESSIONAL PRODUCTS CO		PO BOX 493	PLEASANTON, CA 945660803
67712	ZODIAC POOL SYSTEMS, INC.		PO BOX 1014	COLUMBIA CITY, IN 46725
71227	SINANEN COMPANY, LTD.		60 AUDUBON ROAD	WAKEFIELD, MA 1880
71661	INTELLIGENT BIOCIDES LLC		122 C ST NW STE 740	WASHINGTON, DC 20001
71903	WD-40 COMPANY		122 C STREET, N.W., SUITE 740	WASHINGTON, DC 20001
72854	AGION TECHNOLOGIES INC.		60 AUDUBON ROAD	WAKEFIELD, MA 1880
73148	ISHIZUKA GLASS CO., LTD.		11400 VANSTORY DRIVE	HUNTERSVILLE, NC 28078
79630	K2 CONCEPTS INC.		1330 CONNECTICUT AVE, NW	WASHINGTON, DC 20036
79705	AIRQUAL CORPORATION		35 INDUSTRIAL DRIVE	CANTON, MA 2021
83315	STERISIL, INC.		835 S. HWY 105, SUITE D	PALMER LAKE, CO 80133
83587	NANOHORIZONS, INC.		200 INNOVATION BLVD., SUITE 242B	STATE COLLEGE, PA 16803
84526	SANOSIL USA, LLC		122 C STREET, NW, SUITE 740	WASHINGTON, DC 20001
85249	HEIQ MATERIALS AG		1369 GWYNEDALE WAY	LANSDALE, PA 19446



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: April 13, 2009

EPA Reg No./ File Symbol

72977-A

Page 1 of 3

Applicant's/Registrant's Name and Address: ETI H2O, Inc.  
1725 Gillespie Way  
El Cajon CA 92020

Product: SDC0240CP

Ingredient: ionic silver (PC 72501) and citric acid (PC 21801)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
			ETI H2O	Own	FN 1
			ETI H2O	Own	FN 1
			ETI H2O	Own	FN 1
			ETI H2O	Own	FN 1
			ETI H2O	Own	
			ETI H2O	Own	FN 1
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	

Signature

*Elizabeth Anne Brown*

Name and Title

Elizabeth Anne Brown  
Steptoe & Johnson, LLP, Authorized Agent

Date

4/13/2009





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: April 13, 2009	EPA Reg No./ File Symbol 72977-A	Page 2 of 3
Applicant's/Registrant's Name and Address: ETI H2O, Inc. 1725 Gillespie Way El Cajon CA 92020	Product: SDC0240CP	
Ingredient: ionic silver (PC 72501) and citric acid (PC 21801)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	FN 2
			ETI H2O	Own	
			ETI H2O	Own	
			ETI H2O	Own	
GENERIC - CITRIC ACID			All data waived by RED; reaffirmed as minimal risk at 68 FR 18550 (4/16/2003)		
GENERIC - SILVER			See attached list	pay	

FN 1: plus new Group A report submitted April 16, 2009 for Axenohl, EPA Reg No 72977-1 (Report No. Axenohl-09-GroupA)

FN 2: Agency letter of 6/21/2001 on EPA Reg No. 72977-1

Signature <i>Elizabeth Anne Brown</i>	Name and Title Elizabeth Anne Brown Steptoe & Johnson, LLP, Authorized Agent	Date 4/13/2009
--	--	-------------------

Companies on 3-31-2009 PDSL to whom Offer to Pay Data Compensation letters were sent:				
707	ROHM & HAAS CO	ATTN: JAMES V. HAGAN	100 INDEPENDENCE MALL WEST	PHILADELPHIA, PA 191062399
10324	MASON CHEMICAL CO		721 W ALGONQUIN RD	ARLINGTON HEIGHTS, IL 60005
18869	KING-HOLLER INT		606 WILSHIRE BLVD SUITE 501	SANTA MONICA, CA 90401
37370	NATIONAL SAFETY ASSOCIATES, INC.		4260 EAST RAINES ROAD	MEMPHIS, TN 38118
37664	TELEDYNE WATER PIK		1730 EAST PROSPECT ST	FORT COLLINS, CO 80521
38688	C. H. DEXTER DIVISION		ONE ELM STREET	WINDSOR LOCKS, CT 6096
39444	KATADYN PRODUKTE	D/B/A KATADYN PRODUCTS, INC.	122 C STREET, N.W., SUITE 740	WASHINGTON, DC 20001
39938	NORTH AMERICAN SYSTEMS, INC.		24700 MILES ROAD	BEDFORD HTS., OH 44146
40810	CIBA CORPORATION		4090 PREMIER DRIVE	HIGH POINT, NC 27265
53735	KING TECHNOLOGY INC.		530 11TH AVENUE SOUTH	HOPKINS, MN 55343
59441	EASTMAN KODAK COMPANY	HEALTH, SAFETY AND ENVIRONMENT	1999 LAKE AVENUE	ROCHESTER, NY 146502208
67619	CLOROX PROFESSIONAL PRODUCTS CO		PO BOX 493	PLEASANTON, CA 945660803
67712	ZODIAC POOL SYSTEMS, INC.		PO BOX 1014	COLUMBIA CITY, IN 46725
71227	SINANEN COMPANY, LTD.		60 AUDUBON ROAD	WAKEFIELD, MA 1880
71661	INTELLIGENT BIOCIDES LLC		122 C ST NW STE 740	WASHINGTON, DC 20001
71903	WD-40 COMPANY		122 C STREET, N.W., SUITE 740	WASHINGTON, DC 20001
72854	AGION TECHNOLOGIES INC.		60 AUDUBON ROAD	WAKEFIELD, MA 1880
73148	ISHIZUKA GLASS CO., LTD.		11400 VANSTORY DRIVE	HUNTERSVILLE, NC 28078
79630	K2 CONCEPTS INC.		1330 CONNECTICUT AVE, NW	WASHINGTON, DC 20036
79705	AIRQUAL CORPORATION		35 INDUSTRIAL DRIVE	CANTON, MA 2021
83315	STERISIL, INC.		835 S. HWY 105, SUITE D	PALMER LAKE, CO 80133
83587	NANOHORIZONS, INC.		200 INNOVATION BLVD., SUITE 242B	STATE COLLEGE, PA 16803
84526	SANOSIL USA, LLC		122 C STREET, NW, SUITE 740	WASHINGTON, DC 20001
85249	HEIQ MATERIALS AG		1369 GWYNEDALE WAY	LANSDALE, PA 19446

# STEPTOE & JOHNSON

ATTORNEYS AT LAW

WRITER'S DIRECT DIAL  
202.419.5166

1330 Connecticut Avenue, NW  
Washington, DC 20036-1795  
Tel 202.429.3000  
Fax 202.429.3902  
steptoe.com

April 20, 2009

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Attention: Marshall Swindell (PM 33)

Re: Application to Register New End-Use Product  
SDC0240CP, File Symbol 72977-A

Dear Marshall:

On behalf of ETI H2O, enclosed please find an application to register a new end-use product. This product is intended to provide control of mold and bacteria in humidifier water tanks. This product is identical in composition to EPA Reg. No. 72977-1 and relies upon data submitted to support that registration; no data are submitted as part of this application. It is similar in labeling to other products registered for this use but containing a different active ingredient (eg., Reg No 41550-1, 13839-120, and 81371-1).

This is not a new use for either of the active ingredients in this proposed product. Both actives have numerous registrations for treatment of water, including water in humidifiers. This application is subject to the Pesticide Registration Improvement Act and is Category A540, as it is a request to register a new pesticide product. Documentation of payment of the service fee is enclosed.

Enclosed with this application please find:

1. EPA Form 8570-1, application form
2. Documentation of payment of the registration service fee (Agency tracking number 74068629769)

Document Processing Desk  
April 20, 2009  
Page 2

3. Confidential Statements of Formula (EPA Form 8750-4) (2 copies)
4. Certification with respect to citation of data (EPA Form 8570-34)
5. Data matrix form (EPA Form 8570-35)
6. Five (5) copies of the proposed labeling

Please contact me immediately at 202-419-5166 or [eabrown@steptoe.com](mailto:eabrown@steptoe.com) if there are any questions about this application.

Sincerely,



Elizabeth Anne Brown, Ph.D.  
Technical & Regulatory Analyst  
[eabrown@steptoe.com](mailto:eabrown@steptoe.com)

cc: ETI H2O

	United States	<input checked="" type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input type="checkbox"/> Other	

**Application for Pesticide – Section I**

1. Company/Product Number 72977-A	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SDC0240CP	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) ETI H2O 1725 Gillespie Way El Cajon, CA 92020  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment – Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification – Explain below	<input checked="" type="checkbox"/> Other – Explain below

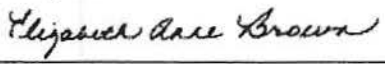
**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Application for registration of new product.

This is PRIA Category A540, service fee \$4,410. Contact point: Elizabeth Brown, Agent for ETI H2O, fax: 202-429-3902, email [eabrown@steptoe.com](mailto:eabrown@steptoe.com). Agency tracking number for payment: 74068629769**Section III**

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
<b>*Certification must be submitted</b>				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 2, 4, 8, 16, 24, 32, and 128 fluid ounce		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

**Section IV**

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Elizabeth Anne Brown		Title Steptoe & Johnson, LLP Authorized agent	
		Telephone No. (Include Area Code) 202-419-5166	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <div style="text-align: center;">(Stamped)</div>
2. Signature 		3. Title Steptoe & Johnson, LLP Authorized Agent	
4. Typed Name Elizabeth Anne Brown		5. Date April 20, 2009	

# Receipt for Section 3

S: 848800

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 72977 ETI H2O, INC.

V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 72977-A

Product Name: SDC0240CP

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 20-Apr-2009



OPP Rec'd Date: 20-Apr-2009



Front End Date: 20-Apr-2009



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

CSF

Paper Label

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 22, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-409004  
EPA File Symbol or Registration Number: 72977-A  
Product Name: SDC0240CP  
EPA Receipt Date: 20-Apr-2009  
EPA Company Number: 72977  
Company Name: ETI H2O, INC.

DOLANA BLOUNT  
ETI H2O, INC.  
1725 GILLESPIE WAY  
EL CAJON, CA 92020

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A532

UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA CITATION EXCEPT FOR PRODUCT CHEMISTRY;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;PRODUCT CHEMISTRY DATA SUBMITTED;REGISTERED ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff  
Information Technology & Resources Management Division



# Fee for Service

{848800Ê~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr.

33

Receipt No.

S-

848800

EPA File Symbol/Reg. No.

72977-A

Pin-Punch Date:

4/20/2009

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

1540

Granted:

1532

Amount Due: \$ 4,410

## Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Lantz/Harbin

Date: 4/21/09

Remarks:



FOR OFFICIAL USE ONLY

FILE SYMBOL

12977-A

REGISTRATION NO.

## CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
4/20/09		

**Do Not Write Comments,  
Formula, or Parts of Formula  
on This Envelope**

### NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Page \_\_\_\_\_ is not included in this copy.

Pages 45 through 46 are not included in this copy.

---

The material not included contains the following type of information:

\_\_\_\_\_ Identity of product inert ingredients.

\_\_\_\_\_ Identity of product impurities.

\_\_\_\_\_ Description of the product manufacturing process.

\_\_\_\_\_ Description of quality control procedures.

\_\_\_\_\_ Identity of the source of product ingredients.

\_\_\_\_\_ Sales or other commercial/financial information.

\_\_\_\_\_ A draft product label.

X\_\_\_\_\_ The product confidential statement of formula.

\_\_\_\_\_ Information about a pending registration action.

\_\_\_\_\_ FIFRA registration data.

\_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_.

\_\_\_\_\_ The document is not responsive to the request.

\_\_\_\_\_ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

\_\_\_\_\_ Attorney-Client Privilege.

\_\_\_\_\_ Claimed Confidential by submitter upon submission to the Agency.

\_\_\_\_\_ Internal Deliberative Information.

---

\* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

---